

USSN: 09/854,824

Docket No.: 56466US002

**REMARKS**

Claims 1-39 are pending in the application. Claim 7 has been amended to correct a typographical error.

**Claim Rejections Under 35 U.S.C. § 102(b)**

Claims 1-5 and 7-16 are rejected under 35 U.S.C. § 102(b) as being anticipated by USPN 5,196,202 to Konishi. Applicants respectfully traverse the rejection.

First, Applicants are unclear regarding which layers the Examiner considers Konishi to disclose. The Examiner cites Konishi for the disclosure of a "drug impermeable layer" and an "adhesive layer." The Examiner also cites materials such as "acrylic copolymers and polyvinyl alcohol" which are characterized in Konishi as the drug release controlling layer, and "conventional drugs such as vitamins, antibiotics and hormones" which are characterized by Konishi as the drug reservoir layer.

Konishi discloses at a minimum, a three layer construction that includes a drug release controlling layer, the drug reservoir layer, and the adhesive layer. Preferably, the device of Konishi is a four layer construction that also includes a drug impermeable layer between the drug reservoir layer and the adhesive layer.

Irrespective of the materials used in the layers provided by Konishi, Konishi fails to disclose "a support layer releasably adhered to the second surface of the carrier" as recited in the independent claims. Konishi requires that all the layers in its device be permanently attached, i.e., "each of these layers is piled in order, glued and dried . . . (Col. 4, lines 3-14 and Example 1(E)). Assuming for purposes of argument that the drug release controlling layer was the support layer (which Applicants dispute), then the ability to releasably detach the drug release controlling layer would change, and potentially destroy, the function of the Konishi multilayer patch.

Konishi fails to disclose a construction of the device in which the support layer is attached to the carrier layer on the surface opposite the adhesive layer, i.e. a construction of 1) releasable support layer, 2) carrier layer, and 3) adhesive layer. Because Konishi fails to disclose every element of claims 1-5 and 7-16, applicants request that the rejections under 35 U.S.C. § 102(b) should be withdrawn.

Claims 15-39 are rejected under 35 U.S.C. § 102(b) as being anticipated by USPN 4,750,482 to Sieverding. The Examiner cites Sieverding to teach "a hydrophilic,

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elastomeric, pressure sensitive adhesive which could be used as a coating on a supportive web-like substrate for delivering an active agent . . .”

Applicants respectfully traverse the rejection. Sieverding fails to disclose a water-soluble or water-dispersible layer. Sieverding specifies that the adhesive is “water-insoluble.” (see, e.g., Abstract and col. 7, line 61). Further, Sieverding fails to disclose any construction of a device in which the support layer is attached to the carrier layer on the surface opposite the adhesive layer, i.e. a construction of 1) support layer, 2) carrier layer, 3) adhesive layer.

Sieverding is concerned with a pressure sensitive adhesive that is “a soft, yet strong, rubber-like solid” that “absorbs moisture that cannot be squeezed out.” Sieverding does not teach or suggest a single layer or combination of layers, each layer capable of dissolving or dispersing once in contact with water. In contrast to the Office Action’s characterization, Sieverding specifies that the adhesive must be water-insoluble. In the uses contemplated by Sieverding (e.g., “a bandage, a burn or wound dressing, a sanitary napkin, an ostomy device . . .” as recited in col. 17 lines 20-27), a water-dispersible layer would be undesirable.

Because Sieverding fails to disclose every element of the claims, Applicants request that the rejections under 35 U.S.C. § 102(b) should be withdrawn.

**Claim Rejections Under 35 U.S.C. § 103(a)**

Claims 1, 4 and 6 are rejected under 35 U.S.C. § 103(a) as obvious over Konishi in view of USPN 5,688,776 to Bauer. The Examiner acknowledges that Konishi fails to teach arabinogalactan but relies on Bauer for that disclosure.

The present rejection of the pending claims does not set forth a case of *prima facie* obviousness. To establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the reference or in the knowledge generally available to one of ordinary skill in the art to modify the reference; there must be a reasonable expectation of success; and the prior art reference must teach or suggest all the claim limitations. Moreover, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Applicants’ disclosure.

As discussed above relating to the 35 U.S.C. § 102(b) rejection, Konishi at a minimum fails to disclose a support layer. Bauer teaches “polysaccharides which are

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crosslinked, and thus no longer water-soluble but are still biodegradable." (see Abstract). Bauer fails to teach or disclose a water soluble/water dispersible carrier layer, water soluble/water dispersible adhesive layer, or a support layer. Thus, the combination of Konishi and Bauer fails to teach all elements of the present invention. Applicants request that the rejections under 35 U.S.C. § 103(a) should be withdrawn.

### Conclusion

In view of the arguments offered herein, Applicants respectfully submit that the Examiner's grounds for objection and rejection are overcome and respectfully solicit reconsideration and withdrawal of the rejections to place the application in condition for allowance.

Registration Number 44,856	Telephone Number (651) 733-2180
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Respectfully submitted,

By Nancy M. Lambert  
Nancy M. Lambert

56446US002 Response to OA 12-16-04  
Office of Intellectual Property Counsel  
3M Innovative Properties Company  
P.O. Box 33427  
St. Paul, Minnesota 55133-3427  
Facsimile: (651) 736-3833